DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

D1197B

FEB 18 1997

WARNING LETTER

FEDERAL EXPRESS

Mr. M. Shabaz Akhtar
Gulmag International
Muhallah Sharif Pura
Kulluwal Road
P.O. Gohadpur
Sialkot, Pakistan

Dear Mr. Akhtar:

During an inspection of your firm located in Sialkot, Pakistan on October 23, 1996, our investigator determined that your firm manufactures surgical instruments. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of the device master record for each type of device to include, or refer to the location of, the device specifications including appropriate drawings, composition, formulation, and component specifications, as required by 21 CFR 820.181(a). For example:

   a. The material composition of each instrument is not identified.

   b. There are no established specifications for dimensions or shape of each device in the device master record.

   Your November 30, 1996, response states that the device master record was revised to include the material composition of each device. Included with the response is a copy of Standard Operating Procedure (SOP) [redacted]

   Your response is not adequate. It appears from SOP [redacted] that you intend to use [redacted] stainless steel. However, the chemical composition listed in the SOP does not have [redacted] for each element. The elemental content listed identifies very specific levels. Provide further information on whether each device manufactured will

contain exactly the identified elemental levels, or whether each device will contain elemental levels in accordance with the [redacted] standard.

The SOP [redacted] also states that each device will be manufactured according to [redacted] provided by the purchaser. Provide further information on whether these [redacted] will contain detailed specifications for each device. Although SOP [redacted] states that a [redacted] is enclosed, there is not one. A [redacted] of the device used as a master sample should be provided.

2. Failure of the device master record to include, or refer to the location of, production process specifications including the appropriate equipment specifications, production methods, production procedures and production environment specifications, as required by 21 CFR 820.181(b). For example:

   (a) The [redacted] chemical composition is not identified in the description of the process.

   (b) There are no hardness testing results from the tempering contractor.

   (c) There are no production procedures identifying at which [redacted] stages during the manufacturing the devices are laboratory analyzed for elemental content.

Your November 30, 1996, response states that the SOP for the [redacted] polishing process has been revised to include the process specifications including the chemical composition. Included with your response is a copy of the SOP for the [redacted] polishing process with the chemical composition.

This response is adequate.

Your November 30, 1996, response also includes a copy of the revised procedure for hardness testing which requires a copy of the hardness testing results from the tempering contractor.

This response is adequate.

Your November 30, 1996, response does not include any information on procedures for laboratory analyzing the devices or steel during [redacted] stages of manufacturing. You provided a copy of the procedures for analyzing the sheet

stainless steel. Provide further information detailing the [redacted] processes during which the devices are analyzed.

This response is not adequate.

3. Failure to check and, where necessary, test for conformance with device specifications each production run, lot or batch prior to release for distribution, as required by 21 CFR 820.160. For example, there are no analysis records or certificates available demonstrating that finished devices are tested prior to distribution.

Your November 30, 1996, response states that an SOP was developed for testing all devices in SOP [redacted]. The procedure outlines a process carried out to sample and analyze all sheet stainless steel at your facility.

Your response is not adequate. It does not include any information on the testing of finished devices. There are no finished device testing, sampling, or process procedures, identified in your response.

The material composition required of the stainless steel is again identified with very specific elemental levels. Provide more information on the process and procedures for finished device testing, and the elemental levels necessary to meet the requirements for release.

We acknowledge that you have submitted a response dated November 30, 1996, concerning our investigator's observations noted on the form FDA 483. We have reviewed your response and have concluded that it is not adequate for the reasons cited above.

Although not a GMP violation, we request that the purchase documents on the stainless steel received from [redacted] be addressed. You provided a certification from [redacted] dated February 10, 1995, batch number [redacted] stating [redacted] stainless steel strip was supplied to [redacted]. With this certification was a material analysis report also from [redacted]. It appears from the device history records provided that the steel was used to manufacture [redacted] batch number [redacted] lot number [redacted]. Please provide further information and/or explanations detailing why steel sold to [redacted] was provided to FDA and used for devices produced at your facility.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and

quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

In order to facilitate FDA in making the determination that such corrections have beer made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device GMP regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's Chief Executive Officer (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The certification of audits and corrections should be submitted to this office by the following date:

- Initial certification by an expert consultant no later than August 30, 1997

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMAs) will be approved and no premarket notifications (section 510(k)s) will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

Your devices are already on detention based on a previous establishment inspection of February 1994. Given the serious nature of these violations of the Act, all devices manufactured by Gulmaq International in Sialkot, Pakistan may continue to be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. Have an outside consultant certify your compliance with the GMP regulations no later than August 30, 1997. After we notify you that your response is adequate, it will be your responsibility to schedule another FDA inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections have been verified, and you are notified that your corrections are adequate, your products may resume entry into this country.

Please notify this office in writing within 15 working days as to the specific steps you have taken, or intend to take to prevent the recurrence of similar violations. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review. Please address your response to:

George Kroehling, Chief
General Surgery Devices Branch, HFZ-323
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Enforcement I
2098 Gaither Road
Rockville, Maryland 20850 USA

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Carol Shirk at the above address or at (301) 594-4595 or FAX (301) 594-4636.

Sincerely yours,

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health